

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: <b>Eva-Karin Anderberg <i>et al.</i></b>	)	Confirmation No. <b>4755</b>
	)	
Application No. <b>10/520,939</b>	)	Group Art Unit: <b>1616</b>
	)	
Filed: <b>January 12, 2005</b>	)	Examiner: <b>Abigail L. Fisher</b>
	)	
Title: <b>Combination of an IBAT Inhibitor and a Metal Salt for the Treatment of Diarrhoea</b>	)	Date: <u>October 20, 2008</u>

AMENDMENT AND RESPONSE UNDER 37 C.F.R. 1.111

In response to the non-final Office Action dated August 18, 2008, the time for responding to which has been extended through October 18, 2008 by the filing of a petition for a one-month extension of time and authorization for fee payment, Applicants respectfully request consideration of the subject application in view of the following remarks. Because October 18 fell on a Saturday, this response is being timely filed on Monday, October 20 under the next business day rule.

Applicants elect with traverse the invention identified as Group I (claims 1-6, 11, 19-24 and 28), directed to a combination of an IBAT inhibitor and a metal salt. Applicants elect with traverse 1,1-dioxo-3,3-dibutyl-5-phenyl-7-methylthio-8-(N-{(R)-1'-phenyl-1'-[N'-(carboxymethyl)carbamoyl]methyl}carbamoylmethoxy)-2,3,4,5-tetrahydro-1,5-benzothiazepine as a first species (the first recited compound of claim 5). Claims 1-3, 5, 9, 10, 11, 15, 19, 20-24, 27, 28 and 32 encompass the first elected species. Applicants also elect with traverse an HMG CoA reductase inhibitor as a second species as recited in claim 19. Claims 1-6, 9, 10, 11, 15, 19, 20, 27, 28 and 32 encompass the second elected species. Applicants note the Examiner's assertion that the

"inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The common technical feature in all groups is IBAT and a metal salt. This element cannot be a


special technical feature under PCT Rule 13.2 because the element is shown in the prior art” (page 3 of the Office Action).

Applicants’ election is with traverse because Applicants submit that the claims of Groups I-IV do relate to a single general inventive concept. The common technical feature in all groups is an IBAT inhibitor and a metal salt, wherein the metal salt is formulated to release in the terminal ileum, caecum and/or the colon as recited in claim 1. Applicants submit that the total features of claim 1 render Applicants’ claims distinguishable over the prior art. Accordingly, Applicants believe that the requirements for PCT Rules 13.2 and 13.1 have been satisfied and request that the outstanding restriction be withdrawn.

**Except** for issues payable under 37 C.F.R. 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. 1.16 and 1.17 which may be required, including any required extension of time fees, or to credit any overpayment to Deposit Account 50-0310. This paragraph is intended to be a **constructive petition for extension of time** in accordance with 37 C.F.R. 1.136(a)(3).

Dated: **October 20, 2008**  
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Respectfully submitted,  
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